UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

MONROE DIVISION

BRYANT LYLES	**CIVIL ACTION NO. 15-0910**
VERSUS	**JUDGE ROBERT G. JAMES**
MEDTRONIC, INC., ET AL.	**MAG. JUDGE JOSEPH PEREZ-MONTES**

RULING

Plaintiff Bryant Lyles ("Lyles") brought this lawsuit as a result of injuries he allegedly suffered after a May 10, 2013 surgery in which his surgeon implanted the Atlantis Translational Anterior Cervical Plate System ("Atlantis Plate").

Pending before the Court is a Motion for Summary Judgment [Doc. No. 80] filed by Defendant Medtronic Sofamor Danek USA, Inc. (a subsidiary of Medtronic, Inc.) ("MSD"). MSD moves the Court to dismiss Lyles' remaining claims under the Louisiana Products Liability Act ("LPLA") that he suffered damage as a result of the defective construction and design of the Atlantis Plate. For the following reasons, the Motion for Summary Judgment is **GRANTED**.

I. FACTS

MSD manufactures and sells the Atlantis Plate, a product which is used as a temporary aid to fusion and to help stabilize the anterior cervical spine (C2-T1) during spinal fusions in patients with degenerative disc disease.[1] The Atlantis Plate consists of two separate metal components which

[1]The federal Food and Drug Administration ("FDA") regulates medical devices. The Medical Device Amendments of 1976, 21 U.S.C. § 360c, *et seq.*, created three classifications (Class I, Class II, and Class III) and imposed a regime of detailed oversight, depending on the risks presented. *See Caplinger v. Medtronic, Inc.*, 921 F.Supp.2d 1206, 1210 (W.D. Okla. 2013), *aff'd,* 784 F.3d 1335 (10th Cir. 2015), *cert. den.*, 136 S.Ct. 796 (2016) (citing *Riegal v. Medtronic, Inc.*, 552 U.S. 312, 315-316 (2008)). The Atlantis Plate is a Class II medical device

are joined by a track and runner system to form one plate. Tiny pins within the track and runner system ensure that the plate components remain intact by preventing the runners on the top component of the plate from coming free of the tracks on the bottom component.

On May 9, 2013, Lyles was admitted to LSU Health Sciences Center Shreveport ("LSUHSC") with complaints of neck and bilateral upper extremity pain, difficulty walking, and complaints of falling and dropping things out of his hands.[2] Lyles had an ataxic gait.[3] An MRI was performed that day and showed severe stenosis[4] behind the C5 body, as well as C4-C5 and C5-C6 disc spaces. Lyles suffered from severe progressive myelopathy with stenosis.[5]

On May 10, 2013, Dr. Anthony Sin performed surgery to decompress Lyles' spinal cord by removing the C5 vertebral body, a procedure known as an anterior corpectomy. During the

---

which was approved under the FDA's § 510(k) process. [Doc. No. 31, Exh. 5]. To obtain approval, the manufacturer must prove that the device is "substantially equivalent" to a medical device that was already cleared by the FDA to be on the market. *Buckman Co. v. Plaintiffs' Legal Comm*., 531 U.S. 341, 345-46 (2001). The substantial equivalency process is designed "to ensure both that medical devices are reasonably safe and effective." *Id.* at 349-50.

[2]Lyles disputes the facts that he suffered from neck pain and complained of falling and dropping things in his hands, but the progress notes of Dr. Richard P. Menger made on May 9, 2013, detail these historical facts. [Doc. No. 80, Exh. 1, Extract of LSUHSC Record, p. 7].

[3]Ataxic gait refers to a person's "[u]stable ability to ambulate or walk around." [Doc. No. 80, Exhibit 2, Dr. Sin Depo., p. 74].

[4]Spinal stenosis is the "narrowing of the vertebral canal, nerve root canals, or intervertebral foramina of the lumbar spine, caused by encroachment of bone upon the space; symptoms are caused by compression of the cauda equina and include pain, paresthesias, and neurogenic claudication. The condition may be either congenital or due to spinal degeneration." http://medical-dictionary.thefreedictionary.com/stenosis, last visited 03/15/2016.

[5]"Cervical myelopathy" specifically refers to "myelopathy due to pressure on the spinal cord." http://medical-dictionary.thefreedictionary.com/myelopathy, last visited 03/17/2016. Myelopathy refers to "any functional disturbance or pathological change in the spinal cord." *Id.*

procedure, Dr. Sin also removed bone spurs and disc material between the disc spaces C4 and C5 and C5 and C6.

Dr. Sin inserted a Verte-Stack implant, which is a vertebral body replacement device, into the C5 cavity to replace the C5 bone that had been removed.[6] Dr. Sin also inserted Progenix, a putty-like bone graft material, mixed with bone dust from the bone and bone spurs which had been removed from Lyles' spine. To hold the Verte-Stack in place and to help stabilize the C4 and C6 vertebral bodies above and below the Verte-Stack, so that fusion could take place,[7] Dr. Sin used four screws to attach the Atlantis Plate to the C4 and C6 vertebrae.[8] The Atlantis Plate is physically stored at LSUHSC, but is retrieved by an MSD sales representative prior to surgery.[9]

Approximately one hour after his surgery, x-rays were taken of Lyles' spine and read by a radiologist. The radiologist did not detect any problems with the Atlantis Plate. [Doc. No. 83, Exh. 1, LSUHSC Record, p. 96].

Lyles was discharged from LSUHSC on May 14, 2013.

On May 20, 2013, Lyles returned to LSUHSC after having been examined at LSU E.A.

---

[6]Dr. Sin sometimes refers to the Verte-Stack implant as a "cage." [Doc. No. 80, Exh. 2, Sin Depo., p. 71].

[7]Dr. Lynn Stringer, Lyles' expert, explained: "For a rigid plate, the purpose would be . . . to hold the bone still while the fusion takes place. And then secondly, with this unique situation where there was a corpectomy replacement cage [the Verte-Stack,] it's to prevent that cage from migrating to the soft tissues of the neck, migrating anteriorly." [Doc. No. 83, Exh. 4, Dr. Stringer Depo., p. 54].

[8]Dr. Sin's notes indicate that the Atlantis Plate is 37.5 mm and was secured by two screws in C4 and two screws in C6.

[9]The parties dispute whether a MSD sales representative actually delivers the device to the operating room. Neither of the two identified sales representatives are listed as being present in the operating room.

Conway. He presented with complaints of increasing pain in the left upper extremity, neck pain, difficulty swallowing; he also reported he had fallen twice since discharge, once falling backwards and hitting his head. According to his surgeon, Dr. Sin, Lyles complained that he had not improved, "which is not that uncommon following a cervical myelopathy related operation in the cervical spine." [Doc. No. 80, Exh. 2, Sin Depo., p. 76].

However, Dr. Sin was concerned that the Atlantis Plate had broken. As a result, radiologic studies were conducted. Dr. Sin studied the x-ray reports, concluded that there was "slight displacement" of the plate, but that it had not broken and had not become unstable. [Doc. No. 80, Exh. 2, Sin Depo., p. 14]. Dr. Sin performed a flexion and extension of Lyles' cervical spine and did not find any instability or any type of displacement. *Id.* at pp. 16, 73.

However, Lyles' C4 and C6 failed to fuse. [Doc. No. 83, Exh. 3, Stringer Report, p. 1; Exh. 5, Mathew Report, p. 2]. The Atlantis Plate is an aid to fusion, but it does not guarantee that fusion will take place. [Doc. No. 83, Exh. 4, Dr. Stringer Depo., p. 56]. During this time, Lyles also continued to suffer pain in his neck and arms, lack of feeling and strength in his hands, and issues with his ability to walk, causing him to suffer additional falls.

On February 6, 2014, Dr. Sin performed a second surgery on Lyles, which consisted of a posterior decompressive cervical laminectomy at C4-C6, followed by insertion of rods and set screws for arthrodesis of C3-C6. Dr. Sin denied that the surgery was performed to correct any condition created by the Atlantis Plate. Specifically, he denied that the slight displacement or dislodgement of the Atlantis Plate was a cause for Lyle's second surgery. [Doc. No. 80, Exh. 2, Sin

Depo., pp. 33, 39].[10] Both the Verte-Stack and the Atlantis Plate placed in Lyles' spine during the anterior surgery remain in place.

According to Dr. Sin, the second surgery was performed to further decompress Lyle's spine through the posterior or back of the spine since he continued to have pain in his neck and his arms and failed to show improvement of his symptoms. *Id.* at p. 76. The surgery was also performed because Lyles' degenerative stenosis and compression affected him posteriorly.

As of Lyles' December 12, 2014 examination, Dr. Sin found that both the anterior and posterior cervical spine have maintained alignment, and there has been "no change in how the [Atlantis Plate] looked compared to his previous imaging studies. [Doc. No. 80, Exh. 2, Sin Depo., pp. 64, 75]. According to Dr. Sin, the Atlantis Plate "never failed." *Id.* at p. 64.

However, Lyles retained an expert to support his case, Dr. W. Lynn Stringer, a neurosurgeon. Dr. Stringer has never met Lyles or examined him or the Atlantis Plate located in Lyles' cervical spine. Dr. Stringer has examined images from Lyles' LSUHSC medical records. Additionally, Dr. Stringer has used the Atlantis Plate in the past, has read the documentation regarding its design and function, and understands how it functions and achieves the intended benefits.

Despite his lack of examination, Dr. Stringer opines that the Atlantis Plate was installed properly and that there was a "mechanical failure" of the plate.[11] [Doc. No. 80, Exh. 3, Report of

---

[10]Dr. Sin admitted that the second surgery was coded in a way that indicated the surgery was necessitated by a reaction to or complication with the Atlantis Plate, but he did not enter the code, and testified "the reason for the operation wasn't anything due to the plate." [Doc. No. 80, Exh. 2, Sin Depo., pp. 38-39].

[11]In his deposition, Dr. Stringer explained that the use of the term "mechanical failure" meant, in this particular case, that "[t]he two halves of the plate are not together. They are interlocking runners. And the runners I assume of the bottom part of the plate are no longer in parallel with the runners of the top part of the plate." [Doc. No. 83, Exh. 4, Stringer Depo., pp.

Dr. Stringer, p. 2]. He opines that "it must be **assumed** [the failure] occurred in the period between the insertion and the xrays done in the recovery room." *Id.* at p. 2 (emphasis added).

During his deposition, Dr. Stringer admitted that he cannot definitively identify the cause of the failure. However, Dr. Stringer testified that he believes that the plate has separated from the runners. He does not know why the plate separated, but testified that "[t]here are little bitty pins that apparently keep the rails in track[,] and there must have been a failure of that. That's all **I assume**." [Doc. No. 80, Exh. 4, Dr. Stringer Depo., p. 41 (emphasis added)]. He agreed with MSD's counsel that he could not "determine why there was a mechanical failure of the plate." *Id.*

Dr. Stringer also opined that the "plate failure was a major contributor to the progression of the spinal deformity and the need for the second operation." [Doc. No. 80, Exh. 3, Dr. Stringer Report, p.2].

Dr. Stringer did not render an opinion as to whether any characteristic of the Atlantis Plate which contributed to its alleged failure existed at the time the Atlantis Plate left the control of MSD. Dr. Stringer did not render an opinion as to the Atlantis Plate's design or as to an alternative design.

MSD retained an expert, Dr. Hallett Mathews.[12] Dr. Mathews, like Dr. Stringer, never examined Lyles, but relied on the record to issue his opinion. He found that the radiographic images from May 20, 2013, showed that "the plate has hyperextended (similar to the alleged fall backwards striking his head)." [Doc. No. 83, Exhibit 5, Mathews Report, p. 1]. In his opinion, the x-ray shows that this hyperextension "appears to have caused the plate to separate from the runners." *Id.* However, in Dr. Mathews' opinion, "it's not possible to say what caused the separation seen on the

---

56-57].

[12]MSD did not cite to Mathews' testimony, but Lyles relies on it in his memorandum.

x-ray" when the Atlantis Plate remains in place in Lyles' spine. *Id.* He thinks that "the evidence shows the plate was disassociated at the evening of the [original] surgery." [Doc. No. 83, Exh. 10, Mathews Depo., p. 112]. He found that the alignment does not appear to have changed significantly based on a comparison of the radiographic images from the night of the first surgery and those taken on May 20, 2013. Although a translational plate, such as the Atlantis, is not supposed to separate, Dr. Mathews pointed out in his deposition that the "safety design of the plate allows it to form to create [sic] a buttress effect." *Id.* at p. 76. Dr. Mathews acknowledges that there was a "[n]onunion," i.e., lack of fusion of the anterior, and a tilting (or kyphosis) at the surgery site. *Id.* at p. 2. However, "[t]his is not an unexpected finding in a smoker with mutlilevel fusion with a corpectomy procedure and 2 documented falls." *Id.*

On January 12, 2015,[13] Lyles' attorney requested that a medical review panel be convened to consider the actions/inactions of LSUHSC and Dr. Sin. [Doc. No. 90, Exhibit 1].

On February 10, 2015, Lyles filed suit against Medtronic, Inc., in the Fifth Judicial District Court, Parish of Franklin, State of Louisiana. On March 26, 2015, Medtronic, Inc., removed the case to this Court. MSD was later added as a Defendant, and the Court dismissed Medtronic, Inc.

II. LAW AND ANALYSIS

A. Standard of Review

Under Federal Rule of Civil Procedure 56(a), "[a] party may move for summary judgment, identifying each claim or defense--or the part of each claim or defense--on which summary judgment is sought. The court shall grant summary judgment if the movant shows that there is no genuine

[13]The letter is dated January 12, 2014, but it refers to Lyles' second surgery having taken place on February 6, 2014, so the date is obviously a typographical error. [Doc. No. 90, Exh. 1].

dispute as to any material fact and the movant is entitled to judgment as a matter of law." The moving party bears the initial burden of informing the court of the basis for its motion by identifying portions of the record which highlight the absence of genuine issues of material fact. *Topalian v. Ehrmann*, 954 F.2d 1125, 1132 (5th Cir. 1992); *see also* FED. R. CIV. P. 56(c)(1) ("A party asserting that a fact cannot be . . . disputed must support the assertion by . . . citing to particular parts of materials in the record . . .). A fact is "material" if proof of its existence or nonexistence would affect the outcome of the lawsuit under applicable law in the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute about a material fact is "genuine" if the evidence is such that a reasonable fact finder could render a verdict for the nonmoving party. *Id.*

If the moving party can meet the initial burden, the burden then shifts to the nonmoving party to establish the existence of a genuine issue of material fact for trial. *Norman v. Apache Corp.*, 19 F.3d 1017, 1023 (5th Cir. 1994). In evaluating the evidence tendered by the parties, the Court must accept the evidence of the nonmovant as credible and draw all justifiable inferences in its favor. *Anderson*, 477 U.S. at 255. However, "a party cannot defeat summary judgment with conclusory allegations, unsubstantiated assertions, or only a scintilla of evidence." *Turner v. Baylor Richardson Med. Ctr.*, 476 F.3d 337, 343 (5th Cir. 2007) (citing *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248 (1986)).

In a bench trial, "a district court has somewhat greater discretion to consider what weight it will accord the evidence." *In re Placid Oil Co.*, 932 F.2d 394, 397 (5th Cir.1991). A court "has the limited discretion to decide that the same evidence, presented to him or her as a trier of fact in a plenary trial, could not possibly lead to a different result." *Id.* at 398 (citing *Nunez v. Superior Oil Co.*, 572 F.2d 1119, 1124 (5th Cir.1978)).

B. Louisiana Products Liability Act

Under the Louisiana Products Liability Act ("LPLA"), LA. REV. STAT. § 9:2800.51, *et seq*, "[t]he manufacturer of a product shall be liable to a claimant for damage proximately caused by a characteristic of the product that renders the product unreasonably dangerous when such damage arose from a reasonably anticipated use of the product . . . ." LA. REV. STAT. 9:2800.54. A manufacturer is liable if its product is found unreasonably dangerous in one of four ways: construction or composition, design, inadequate warning or nonconformity with an express warranty. *Id.*; *see also Holloway v. Midland Risk Ins. Co.*, No. 36262-CA (La. App. 2 Cir. 2002), 832 So.2d 1004, 1011 (citing *Young v. Logue*, 94-0585 (La. App. 4 Cir. 5/16/95), 660 So.2d 32). Lyles asserts claims that the Atlantis Plate was defective in construction or composition and in design.

MSD moves for summary judgment on all remaining claims, contending that Lyles cannot establish that (1) the Atlantis Plate contained an unreasonably dangerous characteristic due to its construction or composition or its design; and (2) that an unreasonably dangerous condition existed in the Atlantis Plate at the time it left the control of MSD.

A plaintiff who contends that a product has a design defect must provide evidence that "[t]he characteristic of the product that renders it unreasonably dangerous" existed "at the time the product left the control of the manufacturer or result[ed] from a reasonably anticipated alteration or modification of the product." LA. STAT. ANN. 9:2800.54 C. Likewise, a plaintiff who contends that a product is unreasonably dangerous in construction or composition must provide evidence that the "characteristic of the product condition that renders it unreasonably dangerous" existed "at the time the product left the control of its manufacturer." *Id.*

1. Defective Design

In order to carry his burden of showing that the Atlantis Plate was unreasonably dangerous and defectively designed, Lyles must show that " at the time the product left [MSD's] control there (1) *existed* an alternative design that was capable of preventing the damage, and (2) the likelihood that the design would cause the damage and the gravity of that damage outweighed the burden on the manufacturer to use a different design." *Batiste v. Brown*, (La. App. 5 Cir. 1/24/12); 86 So.3d 655, 660 (emphasis added).

In this case, Lyles admits in response to MSD's statement of material facts that he lacks proof of an alternative design. Accordingly, MSD's Motion for Summary Judgment on Lyles' design defect claim is GRANTED, and this claim is DISMISSED WITH PREJUDICE.

2. Defective Construction

Under Louisiana Revised Statute 9:2800.55, "[a] product is unreasonably dangerous in construction or composition if, at the time the product left its manufacturer's control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer." A plaintiff must "demonstrate not only what a manufacturer's specifications or performance standards are for a particular product, but how the product in question materially deviated from those standards so as to render it 'unreasonably dangerous.'" *Morris v. United Services Auto. Ass.*, 32,528 (La. App. 2 Cir. 2000); 756 So.2d 549, 558. When a plaintiff fails to produce evidence of specifications and performance standards, and deviation therefrom, he fails to prove his case. *See e.g. Ashley v. Gen. Motors Corp.*, 27,851 (La. App. 2 Cir. 1/24/96), 666 So. 2d 1320, 1322 (holding that plaintiffs failed to prove the accelerator system of their car was unreasonably dangerous due to its construction or

composition where they offered no evidence regarding specifications and performance standards for the accelerator system or that the system deviated in any fashion from the identical system installed on similar cars.); *Broussard v. Biomedical Enterprises, Inc.*, 2014 WL 1323213, at *1 (W.D. La., Mar. 28, 2014) (granting unopposed motion for summary judgment on a claim that a medical device was unreasonably dangerous in its construction or composition, where the device remained inserted in the plaintiff's foot and no testing of the device had occurred to establish that the product deviated in a material way from specifications or performance standards.)

In this case, the Atlantis Plate remains in Lyles' spine and, accordingly, has not been subjected to testing. Dr. Stringer, Lyles' only expert, admits that he cannot render an opinion on MSD's specifications or performance standards for the Atlantis Plate or how the particular Atlantis Plate used in Lyles' surgery materially deviated from those specifications and performance standards.

Additionally, although Dr. Stringer assumes that a mechanical failure occurred some time after surgery, but before Lyles left the recovery room, he does not know. Likewise, he cannot offer an opinion on what happened with the pins and tracks of the Atlantis Plate, what caused the separation, and what caused the plate to allegedly fail. Finally, he cannot render an opinion on whether the mechanical failure occurred before the Atlantis Plate left the control of MSD. Therefore, Lyles cannot meet his burden on proof based on his expert's testimony.

To address these deficiencies in the evidence, however, Lyles argues that he can rely on the doctrine of *res ipsa loquitor* to show that the construction or composition of the Atlantis Plate used in his surgery was defective at the time it left the control of MSD.

"The principle of res ipsa loquitur is a rule of circumstantial evidence that infers negligence on the part of defendants because the facts of the case indicate that the negligence of the defendant

is the probable cause of the accident, in the absence of other equally probable explanations offered by credible witnesses." *Montgomery v. Opelousas Gen. Hosp.*, 540 S.2d 312, 319 (La. 1989) (citations omitted). Because it is "'a qualification of the general rule that negligence is not to be presumed,'" it "must be sparingly applied." *Spott v. Otis Elevator Co.*, 601 So.2d 1355, 1362 (La. 1992) (quoting *Day v. National U.S. Radiator Corp.*, 128 So.2d 660, 665 (La. 1961)). However, a plaintiff generally may use the doctrine of *res ipsa loquitur* "to establish that a product is unreasonably dangerous, and thus, defective" when that product left the manufacturer's control. *Lawson v. Mitsubishin Motor Sales of America, Inc.*, 2005-0257 (La. 9/6/06); 938 So.2d 35, 47, 49. As the Louisiana Supreme Court explained:

> We see no reason why a plaintiff cannot use circumstantial evidence in order to make the inference that a product was unreasonably dangerous when that product left a manufacturer's control. This inference merely shifts the burden of proof to the defendant-manufacturer, such that the manufacturer must prove that the product was not defective when it left the manufacturer's control. The defective nature of a product will not be "presumed" by utilizing this doctrine, but rather, "[i]t simply gives the plaintiff the right to place on the scales, 'along with proof of the accident and enough of the attending circumstances to invoke the rule, an inference of [the unreasonably dangerous nature of a product]' sufficient to shift the burden of proof."

Id. at 49 (quoting *Cangelosi v. Our Lady of the Lake Reg. Med. Ctr.*, 564 So.2d 654, 660 (La. 1989) (alteration in the original)).[14]

In order to invoke the doctrine of *res ipsa loquitur*, the plantiff must establish the following:

(1) the facts must indicate that the plaintiff's injuries would not have occurred in the absence of negligence;

---

[14]The product at issue in *Lawson* was not a medical device, and the Louisiana Supreme Court has not addressed whether a plaintiff can use *res ipsa loquitor* to show that a product was unreasonably dangerous when it left the manufacturer's control if the product is a medical device regulated by the FDA.

> (2) the plaintiff must establish that the defendant's negligence falls within his scope of duty to plaintiff; and
>
> (3) the evidence should sufficiently exclude inference of the plaintiff's own responsibility or the responsibility of others besides the defendant in causing the accident.

Id. at 50. With regard to the third criterion, a plaintiff need not negate all possible causes, but he must present evidence that "excludes other reasonable hypotheses with a fair amount of certainty." *State Farm Mut. Auto. Ins. Co. v. Wrap–On Co., Inc.*, 626 So.2d 874, 877 (La. App. 3 Cir. 1993). That is, a plaintiff's evidence is sufficient when "the only reasonable and fair conclusion is that the accident resulted from a breach of duty or omission on the part of the defendant." *Jurls v. Ford Motor Co.*, 2000–32,125, p. 8 (La. App. 2 Cir. 1/6/00); 752 So.2d 260, 265. When "reasonable hypotheses as to other causes" of the plaintiff's injuries remain, a plaintiff may not rely on *res ipsa loquitur*. *See Ayala v. Enerco Group, Inc.*, —— Fed.Appx. ——, 2014 WL 2200642, at *7–8 (5th Cir. May 28, 2014)(unpublished, per curiam).

> The doctrine is applicable when plaintiff's accident is best explained by defendant's negligence and not some other factor. "The basis on which this conclusion is drawn is usually knowledge common to the community as a whole, although in cases such as medical malpractice expert testimony may be used to establish this principle." Furthermore, "[a]pplication of the principle is defeated if an inference that the accident was due to a cause other than defendant's negligence could be drawn as reasonably as one that it was due to his negligence." Plaintiffs bear the burden of excluding reasonable explanations for the accident other than defendant's negligence.

Ridgeway v. Pfizer, Inc., No. CIVA 09-2794, 2010 WL 1729187, at *3 (E.D. La. Apr. 27, 2010) (quoting *Cangelosi*, 564 So.2d 666) (other citations omitted).

Here, Lyles alleges that the Atlantis Plate manufactured by MSD separated, so that it failed to promote fusion and resulted in an additional surgery. He contends that the doctrine of *res ipsa loquitor* applies because (1) the radiographic images taken shortly after surgery appear to show the

separation of the Atlantis Plate, (2) the experts who reviewed the case did not find an unusual event or that anything went wrong during the surgery, and (3) the Atlantis Plate was allegedly in MSD's control until the moment of surgery.[15] However, Lyles continues to assert a malpractice claim against his surgeon, Dr. Sin.

After review of the record presented, the Court finds that the doctrine of *res ipsa loquitor* is inapplicable because Lyles has failed to sufficiently exclude inference of his own responsibility or the responsibility of others in causing his injuries. No one has access to the Atlantis Plate still implanted in Lyles' spine. None of the physicians--neither the surgeon nor the two experts--can identify the cause of the shifting or misalignment of the plate. Dr. Sin believes that Lyles' Atlantis Plate became slightly dislodged or misaligned when it hyperextended as a result of his post-surgical falls, but also testified that it continues to perform its function. The two experts believe that the Atlantis Plate became misaligned on the date of surgery, but neither expert can identify the cause of the misalignment. Although x-rays were apparently taken during surgery, they could not be located, so there is no evidence that the plate was misaligned at that point. Dr. Stinger admittedly "assumed" the misalignment took place after surgery and "assumed" there was a problem with the pins, but failed to address any of the reasons for the bending or breakage of the plate identified in the package insert, such as whether the proper size was selected, surface scratching or notching, placement of the implant, and stresses caused by the patient's post-operative movement. Therefore, Lyles cannot rely

[15]Given the Court's conclusions, it need not reach the issue of whether the Atlantis Plate remained in the control of MSD because a MSD sales representative may or may not have presented the plate in the operating room itself. The Court would note, however, that even if the MSD sales representative had placed the plate in the hands of Dr. Sin immediately prior to surgery, there is no evidence as to where the Atlantis Plate was stored at LSUHSC and who had access to that storage area.

on Dr. Stringer's testimony to sufficiently exclude other reasonable explanations for the misalignment of the Atlantis Plate that are identified in the package insert.

Additionally, in a separate lawsuit, Lyles asserts that Dr. Sin committed malpractice by improperly installing a medical device which itself could have caused the misalignment (as well as asserting claims that Dr. Sin implanted a defective device and improperly monitored Lyles). Thus, he has also failed to exclude evidence that his injuries were the result of the actions of Dr. Sin, rather than a defect in the Atlantis Plate.

While Lyles has offered some "possible assumptions," [Doc. No. 80, Stringer Depo., p. 41], he has not met his burden to rely on the doctrine of *res ipsa loquitur* to provide an inference of negligence on the part of MSD. Therefore, he has failed to establish that the Atlantis Plate which remains in this cervical spine was in an unreasonably dangerous condition at the time it left the control of MSD. If this same evidence were presented to the Court at the upcoming bench trial, the Court could reach no different conclusion.

III. CONCLUSION

For the reasons set forth, MSD's Motion for Summary Judgment [Doc. No. 80] is **GRANTED**, and Lyles' claims are **DISMISSED WITH PREJUDICE**.

MONROE, LOUISIANA, this 23rd day of March, 2016.

ROBERT G. JAMES
UNITED STATES DISTRICT JUDGE